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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,989	01/22/2004	Gary Berg	P-4998.03	8234
27581	7590	12/07/2005	EXAMINER	
MEDTRONIC, INC. 710 MEDTRONIC PARK MINNEAPOLIS, MN 55432-9924			EVANISKO, GEORGE ROBERT	
			ART UNIT	PAPER NUMBER
			3762	

DATE MAILED: 12/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/763,989

Applicant(s)

BERG ET AL.

Examiner

George R. Evanisko

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 and 20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-17 and 20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10, 16, 17, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Sholder et al (4989602). Sholder teaches the use of a pacemaker delivering pacing pulses and communication/data pulses that are of “insufficient energy to invoke a cardiac response” (abstract and columns 4 and 13) to be received by the receiver (sensing circuit) in the “external” AICD device. It is noted that the examiner has interpreted the claim language of “external” in its broadest reasonable interpretation of a device that is outside or exterior to the pacemaker. Finally, for claims 16 and 17, the communicated data is considered to be patient data and device specific data since it represents the devices sensing of a patients arrhythmia.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 10, 14, 16, 17, and 20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sholder et al (5899928). Sholder discusses the use of a magnet and reed switch to trigger generation of the second stimulation pulses in column 11. In addition, Sholder shows in Figure 7C the use of a subthreshold signal, 330-340, that will prevent substantial physiological effects and is insufficient to capture cardiac tissue since the signal occurs during the refractory period and will not be above the patients stimulation threshold and cause stimulation (also see Sholder, column 15, lines 45-60). In addition, Sholder provides device and patient data with the second signal (column 13). Finally, Sholder teaches the use of amplitude modulation, frequency modulation (pulse number or interval modulation), and pulse width modulation in columns 5 and 16.

In the alternative, Sholder discloses the claimed invention except for the second signal being a subthreshold signal being insufficient to capture cardiac tissue and corresponding receiver to receive the subthreshold signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the communication system as taught by Sholder, with the second signal being subthreshold and insufficient to capture cardiac tissue

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and corresponding receiver to receive the subthreshold signal since it was known in the art that implantable communication systems use the second signal to be subthreshold and being insufficient to capture cardiac tissue to provide communication signals that are below the stimulation threshold and that do not cause any ill effects and are safe to the patient and to use a receiver to receive the subthreshold signal to allow an external device to interpret the communication data from an internal device.

Claims 2-8, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sholder et al ('928).

Sholder discloses the claimed invention except for the signals being biphasic (claims 2 and 11) and therefore include circuitry to control the polarity of the pulse (claim 8) and the signal including marker channel information (claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Sholder, with the signals being biphasic and the signal including marker channel information since it was known in the art that implantable systems use signals that are biphasic (and therefore include circuitry to control the polarity of the pulse) to provide no net charge to the electrode/body and/or prevent the electrode from degrading and since it was known to provide the internal communicated signal with marker channel information to allow the physician to verify the proper operation of the implanted device.

In addition, to the pulse frequency (pulse number or interval) modulation presented in the 102/103 rejection above, Sholder discloses the claimed invention using pulse number or pulse interval modulation except he doesn't disclose (call it) pulse frequency modulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the implantable system as taught by Sholder, with the use of pulse frequency modulation since it was known in the art that implantable systems use pulse frequency modulation for communication of data to provide a conventional communication protocol that is easily understood, received, and processed by conventional circuitry.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6704602. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader application claims. It is noted that the patented claims perform the method steps. Also, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the pulses being biphasic and at levels relating to cardiac tissue, the external device triggering the internal pulse generator, delivering the second signal relative to the cardiac cycle, and the transmitted data to be marker channel, electrogram, or device data since it was known in the art that implantable stimulators use the pulse being biphasic and related to level for

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cardiac tissue to provide a charge balanced pulse and to provide therapy and communication while using a pacemaker, the external device triggering the internal device so the internal device only delivers the data when necessary to prevent power loss, delivering the second signal relative to the cardiac cycle so as to prevent fibrillation, and the transmitted data to be marker channel, electrogram, or device data to allow the physician to verify the device is operating properly.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The argument that the distinction between the pulse being subthreshold and at a level sufficient to capture cardiac tissue applies regardless of when the pulse is delivered (that is, "an above threshold pulse will not capture during a refractory period...and a below threshold pulse will not capture even if, e.g. cardiac cells are polarized") is not persuasive since these limitations were not claimed. Sholder, '928, shows the pulses being delivered during the refractory cycle and therefore are "subthreshold", won't capture cardiac tissue, and prevent physiological effects. The argument that Sholder, '928, requires all generated signals to be above threshold, Col 12, lines 25-35, is not persuasive since column 12, lines 25-35, deal with a different embodiment using eight pulses, and not the embodiment shown in figure 7C of delivering the pulses during the refractory period. In addition, Sholder, '928, meets the broad limitations in the claims of being a "subthreshold level" pulse. Also, a 103 rejection is provided showing that it is well known to provide the pulses as subthreshold pulses and the receiver detecting the subthreshold pulses. Funke is a showing of the use of an external receiver to detect the subthreshold pulses and using subthreshold pulses to transmit data.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Funke and Sholder ('602) are two examples of many showing the use of the second signal being subthreshold and below the first signal. In addition, Funke is one example showing the use of an external device to detect the subthreshold pulses.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

12/4/5

GRE
December 4, 2005